LEADING EDGE OR BLEEDING EDGE? CRB ADOPTS DAUBERT IN "EXPERIMENTAL" SURGERY CASES by Michael R. Kerin

If we continue to develop our technology without wisdom or prudence our servant may prove to be our executioner. Omar N. Bradley

Be not the first by whom the new are tried, nor yet the last to lay the old aside." Pope, Alexander, Essay on Criticism, Part II, Line 126

When you're living on the bleeding edge, you should not be surprised when you do, in fact, bleed. Unknown

History is replete with examples of the law scrambling to adapt to the unforeseen consequences of emerging technologies; allowing enough of the genie out of the bottle to do its good work, but not so much that the technology can run roughshod over its user. The internet has afforded many recent examples of legislators and jurists grappling with new challenges foisted upon them by the arrival of this new technology. Existing laws have not proven elastic enough to encompass the novel challenges posed by a technology which made it possible freely to download pirated music or child pornography, so new laws have been promulgated in an effort to establish the delicate balance necessary to allow the benefits of the new technology's leading edge but to minimize the lacerations of its bleeding edge.[1]

The world of workers' compensation is not exempt from the difficulties presented by technological advances outpacing the law. Recently the CRB had several opportunities to wrestle with the issue of emerging technology in the context of reviewing trial commissioners' decisions in cases involving an unconventional surgical procedure, namely a multi-level disc replacement. In *Vannoy-Joseph vs. State* 5164 CRB-8-06-11 (1-29-2008), the legal issue before

the CRB was a determination of what scientific evidence is required for a trial commissioner to find that a new medical procedure is reasonable and necessary in accordance with C.G.S. § 31-294d, which provides in relevant part: "The employer shall provide a competent physician or surgeon to attend the injured employee and, in addition, shall furnish any medical and surgical aid…as the physician or surgeon deems reasonable or necessary." Id.

In order to understand the new direction charted by the CRB in *Vannoy*, it is helpful briefly to examine the course it has already navigated in several other decisions. In *Pagliarulo v. Bridgeport Machines*, 20 Conn. App. 154, 159 (1989) *citing*, *Acquarulo v Botwinik Bros*., 139 Conn. 684 (1953), the Court held:

> Reasonableness of treatment goes beyond the ordinary knowledge of the trier of fact and may require expert testimony. The question is not only a medical matter but is also affected by a consideration of the surrounding circumstances as the trier of fact finds them. Such circumstances may include the claimant's age, medical history, previous course of treatment and its success or failure and whether the proposed medical procedure involves real danger and suffering without assurance of effecting improvement or restoration of health. *Id*.

. In Cirrito *v. Resource Group Ltd. Of Conn* 4248 CRB-1-00-6 (June 19, 2001), the CRB held that if a physician believes that a particular type of treatment is worth attempting, the Workers' Compensation Commissioner would normally be justified in approving such treatment, even if the effective rate for the proposed procedure (a series of epidural injections) is 5% or less.

Another waypoint offering some direction in the discussion of what constitutes "reasonable and necessary" treatment is *Irizzary v. Purolator Currier Corp*. 4382 CRB-4-01-4 (May 2, 2002), in which the CRB held "there is nothing in §31-294d limiting 'reasonable and necessary' medical care to courses that will probably be

successful, nor would the humanitarian spirit of the workers' compensation act be furthered by our reading of such a limitation into a statute." In that case, the CRB affirmed a trial commissioner's approval of a multi-level lumbar fusion surgery deemed a "salvage" operation by the treating physician and the commissioner's examiner.

While these decisions may serve as an instructional guide to the case law involving reasonable and necessary treatment for widely-approved medical procedures, they do not address the issue of what standard should be employed in cases in which a claimant is requesting an experimental procedure. The CRB was confronted with that precise issue in *Jolicoeur vs. Duncklee, Inc*. 5150 CRB-2-06-10 (November 2, 2007) in which it upheld the trial commissioner's denial of a four-level disc replacement based on the commissioner's finding that the device, which had been approved by the FDA for one level only, "involved real danger and suffering without fair assurance of improved or restored health." *Jolicoeur*, Id. The CRB relied upon the old language in *Acquarulo*, exhuming possible concerns the trial commissioner may have had with respect to an experimental surgical procedure, but deferred articulating a new standard for the trial commissioner's evaluation of scientific evidence.[2]

It did not have to wait long before opportunity came knocking again. In *Vannoy-Joseph*, the CRB was asked to overturn a trial commissioner's finding authorizing the treating physician to conduct a three-level disc replacement based on the respondent's argument that the trier had exceeded his authority by finding that this surgical procedure was reasonable and necessary, since it had

not been approved by the FDA and posed significant costs and risks, and further, a private health insurer would be entitled to deny this procedure as experimental.

In its carefully reasoned analysis, the CRB set a new course heading by outlining the criteria a commissioner must use in reviewing the scientific evidence in a case involving a new medical procedure. The new standard enunciated by the CRB in this case is that when considering approval of a contested surgical procedure, the commissioner must "take steps to verify that a physician's methodology is reliable, and relevant to the case." *Vannoy-Joseph*, at 15. In doing so, the CRB adopted the criteria of the landmark decision of *Daubert v. Merrell Dow Pharmaceuticals, Inc*. 509 U.S. 579 (1993) in which the Supreme Court rejected the then 70 year old *Frye* standard which barred an expert opinion based on scientific technique unless the technique is "generally accepted" as reliable in the relevant scientific community.

The *Daubert* Court ruled instead that the trier should make a determination as to whether the testimony underlying the reasoning or methodology is scientifically valid and can be properly applied to the facts at issue. If the trier finds the methodology valid, he or she may allow the jury to consider this evidence. This relaxing of the heretofore uncompromising "general acceptance" standard was a result of the Federal Rules of Evidence, especially rule 702, which came into effect in 1975. Specifically, rule 702 assigned to the judge the task of insuring that an expert's testimony rests on a reliable foundation and is relevant to the task at hand. The *Daubert* Court was quick to note that there was

nothing in the text of the rule that required a “general acceptance” or *Frye* standard.

Instead, the Court stated that there were four non-exclusive categories under which the trier must make his/her inquiry in assessing whether the underlying methodology is scientifically valid. First, has the theory or technique been tested?; second, has it been subjected to peer review and publication?; third, what is its known or potential error rate and the existence and maintenance of standards controlling its operation?; fourth, has it attracted widespread acceptance within a relevant scientific community? The Court also emphasized that this inquiry was a flexible one and that the focus should be on the methodology and principles rather than on the conclusions that they generate. *Id.*

The CRB in *Vannoy-Joseph* also references the Connecticut Supreme Court’s adoption of the Daubert standard in *State vs. Porter*, 241 Conn. 57 (1997) where the Court adopted the four criteria established in *Daubert* for determining whether a particular theory or technique is based on scientific knowledge.

The new *Daubert/Porter* standard provides a chart for practitioners to follow in navigating a course in cases involving leading edge medical procedures. It is clear that in order for a claimant to prevail in such a case it is not enough that the treating physician testifies that the new procedure is safer, more effective and cost efficient for the trial commissioner to find that the procedure is reasonable and necessary; rather, the claimant must provide scientifically tenable reasoning in the record to support the medical evidence. *Vannoy*, at 19. When there is a dispute over a method of treatment that does not enjoy general acceptance in the

scientific community, the trial commissioner "must carefully examine the methodology underlying the proponent health care provider's opinion." I*d*.at 13.

The factors which are relevant to the commissioner in making such an examination include the quality of testing and peer review given to the reasoning or technique, its known and potential rate of error, to what degree conclusions rely on subjective assessments rather than objectively reliable criteria, and the background of the doctor. *Id*. at.16

The CRB dismissed the respondent's deceptively appealing argument that because the proffered procedure was not FDA approved, and would probably not be FDA approved for at least 25 years, the procedure could not be deemed reasonable and medically necessary. The CRB reasoned that just because a three level disc replacement is an "off label" use of this particular device, that does not mean that it is off limits[3]. Specifically, the CRB ruled that "the absence of FDA approval for a physician's proposed "off-label" use of a legally marked device should not be treated as a proxy for a factual determination that the "off-label" use would be unreasonable even though the FDA-approval history in labeling of the device may in some cases provide valuable evidence or fitness of unfitness for a suggested use." *Vannoy-Joseph* at 11.

The CRB was equally unpersuaded by the testimony of the treating physician who, although providing evidence supporting the validity of the proposed three level procedure, did not provide the level of scientifically sound evidence required under the new Daubert standard. As such, the CRB remanded the case for the limited purpose of introducing scientifically competent evidence, which if adduced

on remand, would strengthen the record enough to allow the authorization of the surgery.

The CRB *seems* to be giving something to everyone in adopting the *Daubert* standard. [4] No longer can the respondents simply argue "it's too experimental." Neither can the claimant rely upon the unclothed opinion of the treating physician that the new procedure is the best course of action. Nor can the commissioner deny a procedure merely by finding it's too dangerous, or approve a procedure holding it's reasonable and necessary. Now the rules are clear. Where a new procedure is in that inchoate stage between experimental and demonstrable, somewhere between the leading edge and the bleeding edge, the claimant has to offer competent scientific evidence based upon a sound and credible methodology to provide a basis for the commissioner to approve such a procedure.

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[1] The term "bleeding edge" is formed as an allusion to "leading edge" and its synonym "cutting edge" but implying a greater degree of risk: the "bleeding edge" is in front of the "cutting edge". Although it is now in common use, the term is somewhat ironic, since the actual bleeding edge of a knife is generally the trailing edge. Wikipedia, The Free Encyclopedia.

[2] In the spirit of full disclosure, this author represented the claimant in his unsuccessful attempt to get a four level disc replacement approved as reasonable and necessary treatment.

[3] The term "off label" usage refers to a device being used in a manner that was not envisaged by the manufacturer's original label, as approved by the FDA, but is nevertheless allowed if the device is being used for any legitimate health care practitioner-patient relationship. *Vannoy,* at 10, citing 21 U.S.C. 396.

[4] Now that the CRB has so exquisitely calibrated our compass with this decision, one hopes that several sentences of the decision do not provide a basis for a magnetic deviation that skews their course. After referencing the criteria a commissioner should use in applying the *Daubert/Porter* standard, the CRB adds: "This is not a checklist. Other factors may be relevant in addition to, or in lieu of, these factors, depending on the specific context." Id. at 15 A reader with a more jaundiced eye might conclude that this sentence provides an exception that swallows the rule, allowing the CRB the latitude to affirm a trial commissioner who can pick and choose from some, or none, of the *Daubert/Porter* criteria. This seed of concern is fertilized by a second sentence in the decision as follows: "As always, the trier of fact need not explain why one methodology is

more persuasive than another. See Admin. Reg. § 31-301-3 (finding should not contain reasons for trier's conclusions, which better suit a memorandum of decision). If the CRB fastens upon this language in future decisions, a trail commissioner can deviate from the *Daubert/Porter* factors, and feel free not to explain his/her reasons for the deviation or why one methodology was more persuasive than another.